RCRA Corrective Action Human Health Assessment

BACKGROUND: This Information Brief presents the basic concepts and essential information for planning and managing human health assessments under the Resource Conservation and Recovery Act (RCRA) corrective action program by owners/operators of hazardous waste treatment, storage, and disposal facilities (TSDFs). The purpose of the RCRA corrective action program is to investigate and remediate (where necessary) routine and systematic releases or discharges of hazardous wastes or hazardous constituents from the solid waste management units (SWMUs) at the TSDF. EPA has indicated that the RCRA corrective action is substantially "equivalent" to the Superfund site investigation/remediation process (55 FR 30810). Therefore, the Risk Assessment Guidance for Superfund, Volume I - Human Health Evaluation Manual, Part A (EPA, 1989) may be followed to perform the baseline risk assessment. In addition to providing guidance on the estimation of health risk, this Information Brief discusses the proper use of media-specific action levels, derivation of health-based cleanup goals, screening/detailed analysis of remedial alternatives, and use of the Corrective Action Management Unit (CAMU) concept to address area or site remediation risk.

STATUTES: Resource Conservation and Recovery Act, as amended by the Hazardous and Solid Waste Amendments (HSWA), Sections 3004(u), 3004(v), 3013, 3005(c)(3), 3008(h) and 7003; and Section 6001 as amended by the Federal Facility Compliance Act (FFCA).

REGULATIONS: 40 CFR 264.101, 264 Subpart F, and 40 CFR 264 Subpart S proposed rule (55 FR 30798, July 27, 1990), and the CAMUs and Treatment Units (TUs) final rule (58 FR 8658, February 16, 1993)

REFERENCES:

1. "RCRA Facility Investigation (RFI) Guidance, Volumes I through IV," Interim Final, EPA/530-SW- 89-031 (May 1989).
2. "RCRA Corrective Action Plan," Interim Final, EPA/530-SW-88-028 (June 1988).
3. "RCRA Corrective action Interim Measures Guidance," Interim Final, EPA/530-SW-88-029 (June 1988).
4. "RCRA Corrective Action Program Guide (Interim)," DOE\EH-0323 (May 1993).
5. "Corrective Action Management Units and Temporary Units" Regulatory Bulletin, RCRA/CERCLA Division (EH-231) (May 1993).
6. "RCRA Corrective Action Interim Measures Under the Proposed Subpart S Rule," DOE/EH-231 (July 1993).
7. "RCRA Corrective Action Permit Requirements and Modifications Under the Proposed Subpart S Rule," Information Brief, EH-231-024/0793 (July 1993).
8. "RCRA Corrective Action Permit Requirements and Modifications Under Subpart F Regulations," Information Brief, EH-231-022/0793 (July 1993).
9. "Implementation of Exposure Assessment Guidance for RCRA," Draft, OSW (September 1993).

What is RCRA corrective action?

RCRA corrective action, as mandated by the Hazardous and Solid Waste Amendments (HSWA), is a process by which a hazardous waste treatment, storage, and disposal facility (TSDF) is investigated and remediated, where necessary, to address routine and systematic releases of hazardous wastes or hazardous waste constituents at the facility. RCRA corrective action is generally required for the TSDF as part of the Part B permit activities conducted by the authorized States or EPA, or through enforcement actions (i.e., RCRA Section 3008(h) orders) by the EPA. **[Update 2/99**: It should be noted that if there is evidence of conditions posing an imminent and substantial endangerment to health or the environment, EPA may choose to issue an order to abate those conditions as quickly as possible under the imminent hazard provisions of Sect. 7003 of RCRA instead of Sects. 3004(u), 3004(v), or 3008(h).**]**

What are the components of the RCRA correction action process?

The process (Figure 1) begins with a RCRA Facility Assessment (RFA). The purpose of the RFA is to identify solid waste management units (SWMUs) or areas of concern (AOCs) where releases have occurred or have the potential to occur. RFA begins with a preliminary review of existing information regarding the facility. If necessary, the review is followed by a visual inspection of potential SWMUs or AOCs to verify information obtained in the preliminary review and to gather information for developing a sampling plan if sampling is required for release determinations.

If the RFA concludes that there has been a release or a potential release, a RCRA Facility Investigation (RFI) will be conducted to characterize the nature and extent of releases of hazardous wastes or hazardous constituents from SWMUs and to determine if the levels in the environmental media pose an unacceptable risk to warrant further action. If the RFI concludes that remediation may be needed, a Corrective Measure Study (CMS) is conducted to confirm the need for remediation, establish remedial goals, and evaluate potential remedial alternatives. The CMS report describes the above activities and may include recommendations for preferred corrective measures.

Through a permit modification or consent order, the selected remedies are implemented during the Corrective Measure Implementation stage of the process, which encompasses

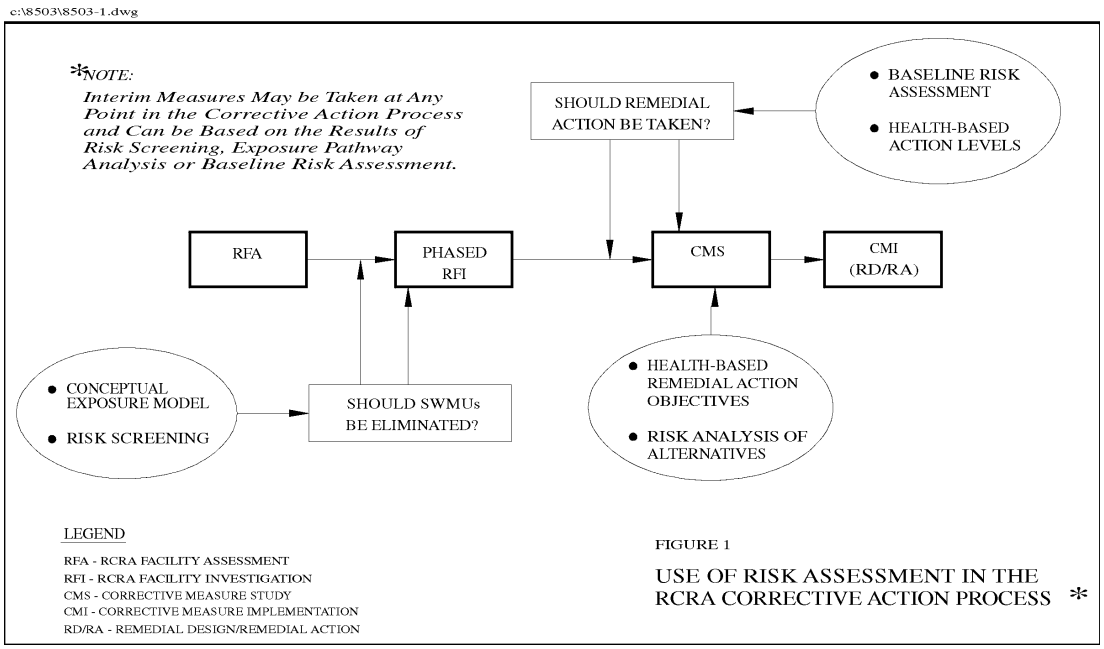

FIGURE 1

USE OF RISK ASSESSMENT IN THE RCRA CORRECTIVE ACTION PROCESS *

remedial design, remedial action construction, and operation/maintenance to satisfy permit requirements or achieve compliance with the consent order.

If SWMUs posing an imminent hazard or a principal long-term threat are identified, interim measures or "stabilization of releases," as called for in EPA's Stabilization Initiative may be conducted to reduce risks.

What are the overall risk management decisions for a RCRA corrective action?

With risk assessment information provided to the environmental restoration program manager (ERPM), the risk management decisions to be made include:

- What is the degree of hazard posed by the site as a whole and the individual SWMUs?
- Is there an imminent hazard or threat which necessitates interim measures?
- What is the major threat, and what is the exposure pathway and population of concern?
- Which SWMU(s) can be eliminated from further action?
- Are the selected interim or final corrective measures able to address the health concerns?
- Are the corrective measures cost-effective, considering uncertainties associated with the risk estimates?

How can human health assessment be used in the RCRA corrective action process?

Risk assessment is the integration of exposure, toxicity and dose-response information. Qualitative and quantitative risk assessment may be used during various stages of the RCRA corrective action process. Moreover, it can be in the form of screening or detailed analysis. The risk assessment tools that can be applied in the RCRA corrective action process are:

A Screening Risk Assessment may be qualitative or semi-quantitative, or a combination of both. It could consist of the following:

- Hazard ranking is an analysis of the volume of hazardous wastes or constituents, their inherent toxicities, release/ leaching and migration potential, exposure routes, and the types or number of receptors - performed to eliminate or prioritize SWMUs.

- A preliminary exposure assessment, based on an understanding of the hazardous waste constituents' chemical and physical characteristics, fate and transport properties, routes of exposure, and types of potential receptors - can be used to establish a *Site Conceptual Exposure Model* for determining completeness of exposure pathways at a SWMU or AOC, and for designing a cost-effective data collection strategy.

- Action levels are chemical concentrations in environmental media determined to be indicators for protection of human health and the environment. Contamination exceeding action levels usually results in a requirement to conduct a CMS. While action levels can be viewed as "screening levels", in the context of the Subpart S proposed rule, they are viewed as a "trigger" for a requirement to conduct a CMS. Action levels are specific to particular chemicals, exposure routes and exposure scenarios, and can be used to compare with RFI data as they are generated.

[There are different types of screening levels; the primary ones are action levels identified in the Subpart S proposed

rule (55 FR 30814, July 27, 1990). EPA Headquarters and certain regions (e.g., III and IX) have also developed screening values or preliminary remediation goals (PRGs) based on a single or multiple exposure routes to humans for residential and industrial/commercial land uses. These levels can also be used to screen SWMUs, if their use has been previously approved by the Regional Administrator or State Regulatory Agency.]

Baseline Risk Assessment may involve multiple-pathways, multiple chemicals, and multiple receptors. Performance of this quantitative assessment is warranted if representative RFI data have exceeded the action levels. The baseline risk assessment focuses on the baseline risk if no corrective measure is taken at the SWMU/groups of SWMUs.

Risk Analysis of Alternatives is performed to evaluate the effectiveness of potential remedial alternatives on the baseline risks and the short-term risks posed by the remedial alternatives (e.g., risk to off-site humans from inhalation of gaseous or particulate emissions from the remedial activities). This analysis is generally qualitative.

Remediation Action Objectives or Cleanup Goals for the hazardous waste constituents may also be derived in the CMS stage by using risk equations from the baseline risk assessment in reverse to calculate chemical concentrations associated with a specific acceptable risk level or hazard. Although these cleanup goals or objectives are health-based, they may not necessarily be the same as action levels used to screen SWMUs or the final media cleanup levels which the selected corrective measure is to achieve. In recommending these goals or objectives, the risk manager takes into consideration the acceptable risk range, uncertainties of the risk assessment, technology, cost, cleanup verification, and other non-risk factors of the site to be remediated.

In addition to the above, the techniques of a risk assessment can be used by the ERPM to justify whether:

- An interim corrective measure is needed in terms of protectiveness and reduction of risks.

- A Corrective Action Management Unit (CAMU)(40 CFR 260.10 and 264.552), identified for management of wastes generated from remediation activities, is appropriate, and will not pose unacceptable remediation risks.

What are proposed Subpart S action levels?

The proposed Subpart S action levels are health- and environmental-based criteria that serve as "indicators" or "screening levels" to generally determine whether a CMS is needed. However, EPA can require a CMS even when the hazardous waste constituent concentrations are below the action levels (e.g., in sensitive environments); and owners/operators may be allowed to demonstrate that a CMS is not needed, even if the media concentrations are above the action levels.

The action levels are specific for four media: groundwater, surface water, soil and air. When available, action levels are set equal to applicable promulgated standards or published guidelines, e.g., drinking water Maximum Contaminant Levels (MCLs) and health advisories, ambient water quality criteria, etc. When such standards or guidelines are not available, heath-based action levels can be calculated according to procedures described in the RFI guidance (see Ref. No. 1) or the Subpart S proposed rule. The comparison of constituent concentrations in all media (except air) are made at and beyond the SWMU where humans may be exposed to the media of concern. Unless humans reside within the facility, the comparison of the air constituent concentration with the action level is made outside the waste management area at the facility boundary.

The proposed Subpart S action levels should not be adopted as cleanup goals or remedial action objectives since they incorporate many conservative exposure assumptions, and do not consider: multiple pathways, implications of action levels due to inter-media transfer (e.g., groundwater seepage into basements causing inhalation hazard for indoor air), chemical interaction or additive effects, site-specific conditions, feasibility of current cleanup technologies, and verification of cleanup.

How current are the action levels published in the RFI guidance, the proposed Subpart S rule, or EPA Guidance?

The action levels published in the Subpart S proposed rule or Section 8.4.2 of the RFI guidance are interim in nature. Their accuracy should be reviewed before the RFI data are compared with the levels. Using the algorithms provided in the above publications, it is recommended that action levels be calculated using the most current slope factors or reference doses from EPA's Integrated Risk Information System (IRIS). This calculation is needed to ensure that the published action levels are current with EPA verified or peer reviewed toxicity information.

If RFI data are below the action levels, what risk assessment information may be needed to justify a no-further action decision?

Even when most or all medium constituent concentrations are below their action levels, a facility with one or more of the following characteristics may require additional risk assessment information to justify a no-further action decision by the regulatory authority.

- Multiple chemicals of concern (COCs)
- Multiple exposure pathways
- COCs and exposure routes known to affect the same target organ system(s) or cause tumors
- Representative and statistically compiled COC concentrations that are close to action levels
- Presence of sensitive environment or receptors

The additional risk assessment tasks may include:

- Exposure pathway analysis based on Site Conceptual Exposure Model
- A site-specific baseline risk assessment
- Derivation of site-specific cleanup goals and comparison of the RFI data with these goals
- An ecological assessment (see "Framework for Ecological Risk Assessment," EPA/630/R-92/001 (EPA, 1992), and

"Risk Assessment Guidance for Superfund, Vol. II - Environmental Evaluation Manual," EPA/540/1-89/001, (EPA, 1989).

What key information is needed for planning a risk assessment conducted in the RCRA corrective action process?

The fundamental principles of risk assessment developed by the National Academy of Sciences (NAS, 1983) should be followed to identify information needs to perform a baseline risk assessment or other components of the risk assessment, i.e., hazard identification, exposure assessment, dose-response and risk characterization. EPA has acknowledged that the RCRA corrective action and the CERCLA programs are substantially equivalent (Subpart S proposed rule, 55 FR 30810, July 27, 1990). Further, Section 8 of the RFI guidance makes numerous references to the CERCLA guidance. Therefore, the Risk Assessment Guidance for Superfund, Volume I - Human Health Evaluation Manual, Part A (EPA, 1989) may be followed to perform the baseline risk assessment. The "CERCLA Baseline Risk Assessment-Human Health Evaluation" Information Brief (DOE/EH-231-012/0692, June 1992) addresses many of the above issues.

Key information required include:

- Constituents or chemicals of concern (COCs):
  - Identification of SWMU or AOC-related chemicals

- Conceptual Exposure Model to identify complete or incomplete exposure pathways:
  - Land use and potential receptors*
  - Patterns of exposure or population characteristics**
  - Release mechanisms and fate/transport properties
  - Exposure media and routes
  - Potentially exposed receptors

[Note: *RCRA generally does not consider on-site workers as potential receptors since they are protected under OSHA (proposed Subpart S rule, 55 FR 30818, July 27, 1990, and the CAMU and TU rule, 58 FR 8658, February 16, 1993); **Exposure information submitted under RCRA Section 3019 should be reviewed.]

- Data Quality Objectives (DQOs) to help ensure the appropriate data (types, locations, quality and quantity) for the risk assessment are collected, validated and compiled:
  - Risk management decisions to be made and the required data types to support decisions
  - Data quality and quantity requirements
  - Data collection strategy and options
  - Validation of collected data (and chemical of concern (COC) selection) by eliminating data which are skewed or fail QC criteria, laboratory contaminants, background and essential nutrient chemicals
  - Statistical compilation of data according to distributional patterns at the exposure points.

- Exposure Intake Factors:
  - Exposure data specific to the SWMU or AOC, and justifications for assumptions for exposure input parameters
  - Exposure estimates for reasonable maximum exposure (RME) and average or the most likely exposure (MLE)
  - Fate/transport modeling (as needed) and model validation

- Critical Toxicity Factors and Their Uncertainties:
  - Reference Doses (RfDs) for noncarcinogens (level of confidence and uncertainty factor)
  - Slope factors for carcinogens (weight-of-evidence)

How should risk estimates be calculated and presented to the decision-maker?

- For the same route of exposure, combine hazards (expressed as hazard quotient, i.e., intake divided by RfD) for noncarcinogens affecting the same organ system(s), and unless demonstrated by synergistic or antagonistic data, combine carcinogenic risks (intake multiplied by slope factor in the linear dose range) for carcinogens

- For multiple exposure routes, hazards or carcinogenic risks can be combined if the toxic effect is the same or tumors are found after exposure via different routes

- Risk Descriptors (central tendency, high-end individual risk***, population risk, and risk to sensitive subgroups)

[***Note: Risk from high end exposure is defined as exposure above 90th percentile of the population distribution but not higher than the individual who has the highest exposure; the Maximum Exposed Individual (MEI) is "worst case" and does not represent high-end exposure ("Implementation of Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities," J. Denit, OSW/EPA, September 24, 1993). In "Guidance on Risk Characterization for Risk Managers and Risk Assessors" (F. Habicht, EPA, February 26, 1992) and the Final Guidelines for Exposure Assessment (57 FR 2288), EPA recognized the use of quantitative uncertainty analysis to establish upperbound risk from high end exposure.]

- Uncertainty Assessment
  - A candid discussion about the level of confidence for site-wide as well as individual SWMU risk estimates
  - Discussions of the weight-of-evidence for carcinogenicity, the confidence level for cancer risk estimates, and the confidence levels for RfDs (noncarcinogenic effects)
  - A discussion of the calculated risk estimates relative to the acceptable risk range, (i.e., 10^{-4} to 10^{-6} carcinogenic risk and hazard index less than unity).

Questions of policy or questions regarding policy decisions are not addressed in EH-231 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief to John Bascietto, RCRA/CERCLA Division, EH-231, (202) 586-7917.